

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Christopher J. M. MEADE et al.

Examiner: Lukton, D.

Serial No.: 10/544,238

Group Art Unit: 1654

I.A. Filed: February 7, 2004

Confirmation No.: 2614

Title: PHARMACEUTICAL COMPOSITIONS BASED ON ANTICHOLINERGICS
AND TACE-INHIBITORS

RESPONSE TO REQUIREMENT FOR ELECTION OF SPECIES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In response to the Office Action mailed November 7, 2006, and the requirement for an election of species therein, applicants hereby elect the species described in Example A)1. (page 33 of the specification) wherein TACE inhibitor compound 2 is of the formula 2a. Regarding the specific requests in the Office Action, this species:

- a) includes the bromide ion of tiotropium,
- b) includes lactose as the sole carrier or excipient,
- c) is in a powder form, and
- d) on information and belief, has a particle of size 5 μm (see comments below on this point).

It is believed that claims 1-5, 12-19 and 35-36 encompass the elected species.

The Election of Species requirement is traversed for the following reasons and particularly as to part d) thereof. Applicants respectfully point out that the application does not provide any disclosure regarding the size of one particle. Thus, applicants only make the above election of a single particle size because they are forced to do so by the Office Action. The size of one single particle is not relevant to the invention and would not be considered of relevance to one of ordinary skill in the art. The 5 µm selection above is made only because that number appears as an endpoint in a disclosed preferred particle size range and is a value in the middle of the broader disclosed preferred particle size range. Applicants fail to see the need for such specificity of particle size nor the need for specificity of a single anion in part a) or a single carrier in part c). It is believed that the purpose of Election of Species practice is to provide an elected scope of invention which is of reasonable breadth to facilitate a search. The specificity required in this election is believed to be much narrower than necessary for a reasonable search. For the fees paid and efforts put forth by applicants in making this application, they are entitled to a much broader search which gives them a reasonable assessment of the patentability of their invention. Thus, the Examiner is encouraged to examine the broadest possible scope of invention indicated by the elected species. It is urged that the search should be much broader than the specificity required in the Election of Species.

In accordance with M.P.E.P. §803.02, should no prior art be found which renders the invention of the elected species unpatentable, the search of the remainder of the generic claim(s) should be continued in the same application. It is improper for the PTO to refuse to examine in one application the entire scope of the claims therein unless they lack unity of invention. The generic claims herein have not been alleged to lack unity of invention.

Regarding the traversal of the previous Restriction requirement, applicants have the

following further comments.

The indication that the method claims are "subject to" rejoinder upon allowance of the composition claims – assuming they are otherwise allowable, e.g., under 35 U.S.C. §112 – is respectfully acknowledged.

Favorable action is earnestly solicited.

Respectfully submitted,

/John A. Sopp/

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